SUMMARY OF THE
QUALITY SYSTEMS COMMITTEE TELECONFERENCE
JUNE 17, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on June 17, 1999, at 1 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (USEPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The list of parking lot issues is currently empty (Attachment C). Attachment D is a listing of frequently asked questions. Attachment E presents the QS Committee approach to handling comments, guiding principles for reviewing comments and the standard, and commenter template. Attachment F contains the QS Committee's response to comments addressed during this meeting. *The purpose of the meeting was to discuss whole effluent toxicity issues, the glossary, and additional comments received by the committee.*

WHOLE EFFLUENT TOXICITY TESTING

The committee reviewed Dr. Peter Delisle's responses to comments from the New Jersey Department of Environmental Protection that pertain to whole effluent toxicity. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.12 of the standard. However, to avoid confusion within NELAC, since version 5.10.7 is the version provided for NELAC V voting, 5.10.12 is only being circulated within the QS Committee at this time (not attached to these minutes and will not be posted on the NELAC Website).

Section D.2.1.a.1.i

The concern was that paragraph i conflicts with the requirements in paragraph ii. Paragraph ii was edited to make it consistent with i. The change was not considered a major issue so it will not be a red tag item. Dr. Delisle's responses are not attached to these minutes as the electronic file could not be read.

GLOSSARY

The committee discussed the definitions and use of the terms *chain-of-custody* and *legal chain-of-custody*. The issues were do these two terms, especially as commonly used in laboratories, refer to the same level of sample handling and custody procedures or should the terms be used to specify different levels of these procedures.

The committee agreed that *chain-of-custody* should be defined as the procedures used to meet legal or evidentiary requirements and the term *legal chain-of-custody* would be deleted from Chapter 5. In addition, sample handling and custody procedures not intended to satisfy legal or evidentiary requirements will be referred to as *sample tracking*, which is addressed in Section 5.12.3. The introductory text for Section 5.12, which addresses records, was revised to include a description of the distinction between *chain-of-custody* and *sample tracking* and Appendix B and Section 5.12.4 were edited to clarify the definition of *chain-of-custody*. This proposed change will be a red tag issue.

Regarding the combined glossary, the committee decided that there was no need to address terms not used in Chapter 5. However, terms used in both Chapter 5 and other chapters of the standard should have the QS Committee definition because they are tied directly to the standards and altering these definitions would affect the standards.

ADDITIONAL COMMENTS

The committee discussed the comments submitted by the organizations listed below, which were initially responded to by the indicated QS Committee member. The individual comments, QS Committee responses, and rationale for the response are presented in Attachment F, unless otherwise indicated.

Severn Trent Laboratories (Mr. Clifford Glowacki):

The committee decided to make no changes to Chapter 5 in response to these comments.

Severn Trent Laboratories (Mr. David Mendenhall):

The committee decided to change the term *MDL* to *A Detection Limit* in Section D.1.4.a. This is not a significant enough change to be a red tag item.

Environmental Laboratory Accreditation Board (Ms. Sheila Meyers):

The committee decided to make no changes to Chapter 5 in response to these comments.

Pennsylvania Department of Environmental Protection (Ms. Mary K. Bruch):

The committee agreed to change the language in Section D.3.1.b.2 to clarify that the requirements apply to a lot of previously prepared media instead of a batch. Ms. Bruch's responses are not attached to these minutes as they are available electronically.

State of New Hampshire Department of Environmental Services (Mr. Slayton):

Mr. Slayton had already sent a letter responding to these comments.

Terry Affiliates (Mr. Donivan Porterfield):

Editorial changes were made in addition to adding a requirement to include the laboratory Standard Operation Procedure number in item 3 of the Demonstration of Capability Certification Statement in Appendix C.

Terry Affiliates (Mr. Scott Siders): In Section 5.12.2.b, the committee clarified the record retention requirements to be 5 years from generation of the last entry in the record instead of 5 years from last use. The term *last use* was potentially confusing. In Section 5.6.2.c.4.v, authentic was deleted from the term *analysis of authentic samples*.

Virginia NELAC Workgroup (Mr. Fred Siegelman):

The committee decided to make no changes to Chapter 5 in response to these comments.

Virginia NELAC Workgroup (Mr. Slayton): An editorial change was made to Section 5.6.3

Proposed changes identified as red tag items are significant proposed changes made since version 5.10.7 of Chapter 5, which will be presented at NELAC V, was sent for publication. Members of the QS Committee will make copies of the compiled red tag changes for distribution at NELAC V.

NEXT MEETING

The next meeting by teleconference is scheduled for June 24, 1999 from 1 p.m. to 3: p.m. EDT and the telephone number is 202-260-8330, access code 4054#.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
JUNE 17, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Slayton to address the issues in the introductory text of the comments from the VA NELAC Workgroup.	June 24, 1999
2.	Mr. Delisle to address the whole effluent toxicity comments from the Virginia NELAC Workgroup.	June 24, 1999
3.	Ms. Bruch to address microbiology comments from VWEA.	June 24, 1999
4.	Mr. Slayton to update Chapter 5 from revision 5.10.11 to 5.10.12 and circulate within the committee.	June 24, 1999

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
JUNE 17, 1999

Name	Affiliation	Phone Numbers
Mr. Joe Slayton	USEPA, Region III, OASQA	T: 410-305-2653 F: 410-305-2698 E: slayton.joe@epamail.epa.gov
Ms. Mary K. Bruch	Mary Bruch Micro Reg. Inc.	T: 540-338-2219 F: 540-338-6785 E:
Dr. Peter Delisle (New member to replace Mr. Porterfield)	Coastal Bioanalysts	T: 804-694-8285 F: E: pdelisle@coastalbio.com
Mr. Raymond J. Frederici (Absent)	Recra Labnet - Chicago	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
Mr. Clifford R. Glowacki (Absent)	Ashland Chemical Company	T: 614-790-3482 F: 614-790-4294 E: cglowacki@ashland.com
Dr. George Kulasin (New member to replace Ms. Meyers)	California Department of Health — ELAP	T: 510-540-2800 F: 510-849-2106 E: gkulasin@dhs.cal.gov
Ms. Sylvia S. Labie (Absent)	Florida Department of Environmental Protection	T: 904-488-2796 F: 904-922-4614 E: labie_s@dep.state.fl.us
Mr. David Mendenhall (Absent)	Utah Department of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Ms. Sheila Meyers	Texas Natural Resource Conservation Commission	T: 512-239-0425 F: 512-239-6307 E: smeyers@tnrcc.state.tx.us
Mr. Jeff Nielson	City of Tallahassee Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Mr. Donivan R. Porterfield	Los Alamos National Laboratory	T: 505-667-4710 F: 505-665-5982 E: dporterfield@lani.gov
Mr. Scott D. Siders	Illinois Environmental Protection Agency	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Dr. Fred Siegelman	US EPA, QAD	T: 202-564-5173 F: 202-564-2441 E: siegelman.frederic@epamail.epa.gov

Name	Affiliation	Phone Numbers
Mr. Mike Cross (Contractor Support)	Research Triangle Institute	T: 202-728-2045 F: 202-728-2095 E: myc@rti.org

Attachment C

PARKING LOT ITEMS/ISSUES
QUALITY SYSTEMS COMMITTEE
JUNE 17, 1999

Items/issues will remain in the Parking Lot until they are completed.

(There are no items/issues in the Parking Lot at this time.)

Attachment D

FREQUENTLY ASKED QUESTIONS
QUALITY SYSTEMS COMMITTEE
JUNE 17, 1999

Some Frequently Asked Questions Concerning NELAC QS (Chapter 5)

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No. QS does not require the use of a specific method/s. Chapter 5 allows the user to select an appropriate method. However, regulatory agencies may mandate the use of a specific method (See also Question 3).

3. Question: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that

it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

6. Question: Why are we revisiting the calibration and detection parts of the standards?

Answer: At NELAC IV the Quality Systems Committee received numerous comments that the calibration and detection parts of the standards were too prescriptive and were not consistent with a PBMS environment. The Committee has attempted to propose changes to the calibration and detection parts of the standards that provide essential elements for those two quality system standards and that will support the anticipated needs of PBMS. The Committee believes the proposed language is less prescriptive (i.e., more flexibility), yet hopefully still ensures the quality of the analytical data.

In making these proposed changes the Committee has attempted to balance the need for more flexibility in the standards with the desire to not go to far and introduce excessive flexibility that could prove to be too vague or ill-advised. The Committee is currently discussing and considering its proposed language and public comments on the proposed language changes. The Committee is committed to assuring that the NELAC Quality Systems standards provide a foundation for PBMS implementation.

7. Question: Several States have indicated that it is very desirable that a laboratory already be actively analyzing samples for a particular program and by a method for which they want to be accredited. However, these same states have relayed that this ideal scenario is often not the case, as a laboratory may request accreditation in attempts to expand their scope of analytical services or in order to satisfy contractual requirements. These states ask: How will the QS standards help ensure that laboratories will have sufficient data for an onsite assessment especially given the proposed changes to the MDL section?

Answer: The MDL, section D.1.4, in the 1998 NELAC standards has a requirement that "MDLs" be determined initially (40 CFR Part 136, Appendix B) and be verified yearly by the analysis of at least one clean matrix sample spiked at the current reported MDL. Under the proposed revision to Section D.1.4, "Detection Limits" are to be determined initially and each time there is significant change in the test method or instrument type. The proposed standard still requires "MDL" if required in the mandated test method or applicable regulation. If the MDL is not required a "detection limit" must still be determined. Therefor the new section D.1.4 requirements should still help assure that performance data will be available for review by inspectors . In addition, laboratories are required to successfully complete two out of three PT samples yearly and this data would be available for review, as per section 5.5.4 and Chapter 2) . However, under the current PT requirements this may only include one method of multiple methods employed by a laboratory for a given parameter group, e.g., metals.

Laboratories also must perform an Initial Demonstration of Analytical Capability (5.10.2.1, D.1.3 Method Evaluation and Appendix C) . This data would be available for on-site review. Also note that the QS committee plans to expand Appendix C (IDC) procedures prior to NELAC V to make it applicable to methods for which spiking is difficult or impossible, e.g., Total Suspended Solids, which should further ensure that performance data is available for review.

In addition under Section 5.6.2.3.c. of QS, the Laboratory Management must ensure that the training of personnel is kept up-to-date, which includes a analyst certification to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year: i. acceptable performance of a blind sample (single blind to the analyst); ii. another initial demonstration of method capability; iii. successful analysis of a blind performance sample on a similar test method using the same technology; iv. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; vi if i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable. These requirements should further help assure performance data is available on-site for review.

Attachment E

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled in by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in by Commentor)** **New Wording for Standard (To Be Filled in by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**

Attachment F

RESPONSES TO COMMENTS
Quality Systems Committee
June 17, 1999

Section	Text	Comments and Proposed Text	QS Leader Provided Change	Rationale
Chapter 5				
5.9.4.2	Sentence 4 - "If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met."	Judgement as to whether requirements in mandated test methods are more stringent, rather than just different, can be arbitrary. **Alternative: Where mandated test methods and/or regulations for calibration exist, the laboratory will follow calibration requirements as specified in**	No Change	Committee added "If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be
5.9.4.2.1 f)	"Results of samples not bracketed by initial calibration standards must be reported as having less certainty,…"	This sounds as if calibration curves are required before and after sample analysis, rather than suggesting that target analyte results reported outside of calibration range must be flagged. This is not appropriate for all analyses, for example, in ICP analyses a linear range	No change	Current version states "Results of samples not bracketed by an initial instrument calibration standards (within
5.9.4.2.1 g)	Sentence 2 – "Data associated with an unacceptable initial instrument calibration shall not be reported."	There may be some cases where reporting such data with a flag is appropriate and better than any alternative available. For example, if one compound in a multi-analyte initial calibration is slightly outside of QC limits, and re-extraction and/or re-analysis is not an option due to lack of available sample and/or holding time, the data would be valid for all points except the one compound, which could be considered estimated or rejected.	QS Committee consensus was to make no change Change to read, "Data associated with an unacceptable initial instrument calibration shall not be reported unless insufficient sample is available for sample reanalysis.	Allows the client to decide if the data are "good enough" for the decision that must be made. Potential reduction of resampling costs.
5.9.4.2.2 b)	"A continuing calibration check must be repeated at the beginning and end of each analytical batch."	Test methods that require this practice to ensure accuracy already contain the requirement. For some test methods, other QC data exist to continuously monitor accuracy (e.g. internal standard response, signal to noise ratio, recovery standards, internal standards, surrogate standards, mass spectral data). In addition, where a calibration curve is already	No change	Only required when initial calibration is not performed on the day of analysis.

5.9.4.2.2 c)	"In each analytical batch the calibration verification checks must include concentrations at the lowest and highest concentration of the initial instrument calibration."	It is unclear as to whether two standards have to be analyzed for each calibration verification instance or is alternating them appropriate? The lowest and highest points are not appropriate for monitoring quantitative accuracy. Calculated results are likely to be either slightly below or slightly above the calibration range of the curve. In both cases, the calculated values would, by definition, have a higher level of uncertainty than values within the curve range and be considered estimated values. Points at which estimated values are likely to be produced are not points at which analytical accuracy should be monitored. It appears that the intent is to monitor two things: quantitative accuracy and the ability to detect a compound at an established quantitation limit.	QS Committee consensus was to make no change **Change to read, "**In each analytical batch the calibration verification checks must include two (2) different concentrations, one above and one below the midpoint of the initial instrument calibration	**The intent of this section is to encourage verification of the initial instrument calibration over the entire calibration range.**
5.10.5 b)	"Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date."	This appears to include all containers, such as empty sample containers, rather than just containers of standards and reagents.	No change	Section title specifies "Standards and Reagents".
5.13 17)	"clear identification of numerical results with values below 3.18 times the MDL.."	**Alternative: "..above or below the quantitation limit".**	No change	Currect version reads "clear identification of numerical results with

Section	Text	Comments and Proposed Text	QS Leader Provided Change	Rationale QS Leader
B Glossary	Legal Chain of Custody Definition.	Because both "Chain of Custody" and "Legal Chain of Custody" are included, there is an inference that one is legal and one is not. Recommend removing legal chain of custody.	Drop the reference to “legal” in chain of custody throughout the standard. See references: Table of contents 5.12.4 ~~Legal/ or Evidentiary~~ Chain of Custody . . . . . 28 **5.12 Records** ... There are two levels of record keeping: 1) sample custody or tracking and 2) ~~legal or evidentiary~~ chain of custody. **5.12.4 ~~Legal/ or Evidentiary~~ Chain of Custody** The use of ~~legal~~ chain of custody (COC) protocols ~~is strongly recommended and~~ may be required by some state or federal programs. In addition to the records listed in 5.12.3 and the performance standards outlined in 5.12.1 and 5.12.2, the following protocols shall be incorporated if ~~legal~~ COC is implemented by the organization. **5.12.4.1Basic Requirements** The ~~legal~~ chain of custody records shall establish an intact,... f) ~~Legal~~ chain of custody shall begin at the point established by the federal or state oversight program. **5.12.4.3 Controlled Access to Samples** Access to all ~~legal~~ chain of custody samples and subsamples shall be controlled and documented. **5.12.4.4 Transfer of Samples to Another Party** Transfer of samples, subsamples, digestates or extracts to another party are subject to all of the requirements for ~~legal~~ chain of custody. Glossary App B **~~Legal~~ Chain of Custody (COC)**: an unbroken trail of accountability that ensures the physical security of samples, data and records...	The two levels of sample handling are sample custody or tracking and CoC
B Glossary	Quantitation Limits Definition: "..with the confidence level required by the data user."	**Alternative: "..at a stated degree of confidence."**	No change	**Changed in a later revision**
B Glossary	Matrix: "the component or substrate which contains the analyte of interest."	The substrate may not contain the analyte of interest. Component, also, has connotations of analyte rather than matrix.	No change.	**Changed in a later revision**

		Alternative: The substrate of the test sample.		
C, IDC, Footnote (1); also D, PBMS Footnote (1)	"Accurate: Based on good laboratory practices consistent with sound scientific principles/practices."	"Good Laboratory Practices" is used as the title of two distinct parts of the CFR, Title 40 Part 160 and Title 40 Part 792. "Based on good laboratory practices" can mean that specific QC requirements have been met under two EPA programs (FIFRA and TSCA). In the context of the sentence, "the data associated with the initial demonstration capability are true, accurate,..." the term representative could be substituted.	No change.	Used in the foot note, the intent is to require a recognized process, an industry standard of practice, etc... that in general is considered "good practice without any reference to a regulatory requirement.
D, D.1.1 b2)	"Matrix Spikes: Shall be performed at a frequency of one in 20 samples…"	The frequency of matrix Specific QC samples should not, and often cannot (due to lack of sample), be determined by a laboratory. Matrix specific QC sample submission and frequency determination needs to be determined on a site-specific basis and followed by the laboratory client. **Alternative: The laboratory shall have procedures for measuring and reporting the effect of the matrix on the method performed**.	No change.	In this section matrix spike is an alternative to LCS as a positive control. If used in place of an LCS the matrix spike must meet the criteria of an LCS, including frequency.

D, D.1.1 b2)	"Matrix Spikes: The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed."	Assignment of matrix specific QC samples based on lab batches results in the information obtained being unusable most of the time. Laboratory batches of 20 samples comprise various clients and sites and matrix QC samples will provide no useable information about the majority of the samples in the batch. Matrix specific QC samples provide crucial information in determination of bias in sample results. This information can only be obtained by using a site-specific approach in matrix specific QC sample assignment. The laboratory is advised in and agency memo, (Clarification Regarding Use of SW-846 Methods, 8-17-98, OSW), "The Agency further recommends that data users should be routinely provided with the MS/MSD results from only those QC samples associated with the field samples from the same site." Controlling matrix QC frequency based on lab batches can result in underestimation of risk at a specific site, where a data user could assume there is no bias of sample results for samples where there is a significant low bias. **Alternative: A laboratory shall have procedures to track client sampling batch and to assist clients in assigning matrix specific QC samples at a frequency of 1 per 20. If clients do not provide MS/MSD at the appropriate frequency, the laboratory will note this in the project report**.	No change.	This describes a workable process used to gather information without placing an undue burden on the laboratory.
D.1.4 a)	"An MDL.."	**Alternative: "A Detection limit.."**	**D.1.4 Detection Limits** A ~~n MDL~~ detection limit study is not required for any component for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen, turbidity or on-line analyses.	Adds to consistency of the standard.

Various	Inclusion of Field activities including QC samples and QC procedures	Field activities have proceeded with limited oversight. A field accreditation standard is essential in providing control of all facets of environmental data generation. While some laboratories provide field sampling services, it is appropriate that they be covered by a separate field accreditation standard just as a field services company would be. In some cases, field activities and field QC samples have been addressed in NELAC, putting the laboratory in the difficult situation of policing its clients. The invested parties appropriate to comment on field activity QC criteria have not been part of the NELAC process. Inclusion of field activities into this standard could lead to a field unit attached to a lab holding an accreditation that field services companies could not obtain on their own. Conversely, it could put an additional burden on field units associated with a laboratory that field services companies do not need to meet. Field testing is an activity that needs to be defined, and a decision should be made as to whether this document covers field testing, including that provided by labs, field service companies, and industry.	No change.	The field sampling issue will be addressed after field sampling becomes an “official” part of NELAC.

Quality Systems Committee April 6, 1999		Source of Comments: ELAB	
Standard Rev. # SECTION# Standard Narrative	**COMMENTwith Rationale to QS**	**QS Leader Provided Proposed Change**	**RATIONAL**
10.1 5.9.4.2.	Change “more stringent” to “different”. Otherwise NELAC will be superseding existing laws, a situation that will never hold up in court. New Wording for Standard: (see last sentence) If ~~more stringent~~ different standards or requirements…..	No change.	The goal of NELAC and the standards for Quality Systems 5 is to develop a MINIMUM set of consencus standards that must be met by the regulated community and participating programs. More stringent requirements would be those that clearly demonstrate greater proficiency defining test results and a greater degree of confidence . These would not supersede existing requirements, they would be add ons to minimum procedures. If it cannot be determined which program is more stringent (NELAC or method and’or program), then the laboratory will use the method or regulatory requirement. If they are so different as to not be comparable, then both would be a requirement. An example of NELAC being more stringent would be the requirement of PE samples for drinking water. The drinking water program requires one per year; NELAC requires 2 sucessful completions per year.

Quality Systems Committee April 6, 1999		Source of Comments: ELAB	
Standard Rev. # SECTION# Standard Narrative	**COMMENTwith Rationale to QS**	**QS Leader Provided Proposed Change**	**RATIONAL**
10.1 5.9.4.2.1 (f)	For certain techniques (i.e., ICP), existing methods allow for a quarterly linear range check and the single point standard does not bracket all of the sample results. This section as written would mean that perhaps 50% of current ICP data would be qualified. New Wording for Standard: Results of samples not bracketed by initial calibration standards, or by quarterly linear range checks in the case of ICP, must be reported as having…	No change.	Consensus drives a minimum of 2 calibration concentration standards for quantiation. Data reported out (unqualified) must be withen this high and low standard.
10.1 5.9.4.2.1 (h)	Frequently in risk assessments, the regulatory/decision level is the MDL. It is not analytically feasible to include a standard at or below the MDL in a calibration curve. In general, the requirement for the low standard in the curve should be that it is at the Quantitation Limit. New Wording for Standard: (We recommend adding another sentence.) However, the lowest calibration standard should not be below the Quantitation Limit.	No change	If program or regulatory requirements mandate the use of an MDL however defined, that will exceed the requirements of NELAC standards if more stringent. This is a program requirement issue. Not an issue for NELAP. If decisions will be made concerning a certain concentration level, then it is required that a laboratory be able to “see” to that level in order to make decisions (decision level). Chapter 5 does not use the term MDL or “minimum detection limit”. Please refer to definitionof “Detection Limit.”

Quality Systems Committee April 6, 1999		Source of Comments: ELAB	
Standard Rev. # SECTION# Standard Narrative	**COMMENTwith Rationale to QS**	**QS Leader Provided Proposed Change**	**RATIONAL**
10.1 5.9.4.2.2 ©	As stated this requirement is a significant deviation from the current practice of running one of the middle points in the curve (typically the second or third point). Since many analytical samples tend to fall in the bottom third of the concentration range, the high standard is of less value for a continuing calibration check than those with lower concentrations. Therefore, our recommendation is that the wording be changed. New Wording for Standard: …must include two concentrations from the…	Change has already been made	Change has been made to the standard to allow laboratories to select 2-calibration verification ranges as long as they are different concentraions

Quality Systems Committee April 6, 1999		Source of Comments: ELAB	
Standard Rev. # SECTION# Standard Narrative	**COMMENTwith Rationale to QS**	**QS Leader Provided Proposed Change**	**RATIONAL**
10.1 5.9.4.2.2 (f)	The statement that a second consecutive calibration check must meet criteria is too restrictive. A typical scenario for volatiles is that when a check fails, the existing standard is rerun. If it's still outside acceptance limits, the standard is reprepared from concentrated stock solutions. If this new check standard passes, the analysis is continued in that the problem was due to instability or volatility of the standards and not due to instrument issues. Thus, three checks could be run before running a new calibration. This is particularly necessary for the "gases" that are part of the volatiles analytes. New Wording for Standard: (second sentence) …within acceptance criteria, a new check standard may be prepared from a fresh stock standard. If this new standard fails, a new initial instrument calibration must be performed.	No change	The typical scenario is acceptable. The second calibration verification check can be at the end of the batch run. This check can also be used to satisfy the calibration verification check for the next batch. Also there has been a rewrite that states only one is required if internal stardards are used.

Quality Systems Committee April 6, 1999		Source of Comments: ELAB	
Standard Rev. # SECTION# Standard Narrative	**COMMENTwith Rationale to QS**	**QS Leader Provided Proposed Change**	**RATIONAL**
10.1 Page 5B-1 - Batch Definition	This definition includes preparation and analytical batches but does not address tests that do not require sample preparation such as water samples for TOX or volatiles analyses. In such a continuous Process with no sample preparation, the batch should be limited to 20 samples with no 24 hour time limit. Otherwise one many never be able to run a full batch of 20 samples even using a continuous autosampler controlled process, if the run time per sample is too long. New Wording for Standard: (add new paragraph) For analytes that do not require sample preparation such as total organic halogens or volatiles, a batch is composed of 20 samples but the time may exceed 24 hours.	No change	Already addressed.

March 29, 1999

Charles Dyer
Program Manager
State of New Hampshire
Department of Environmental Services
6 Hazen Drive
P.O. Box 95
Concord, NH 03302-0095

Dear Mr. Dyer:

On behalf of the QS committee I would like to thank you for your letter and the comments from Russell D. Foster, Technical Director, RLI Resource Laboratories, Inc and from SCITEST Laboratory Services (Joann). We request that in future submissions that you employ the comments template that QS's has routinely included with our meeting minutes on the NELAC Web page.

1. Definition of Preparation Batch, appendix B, page 5B-1. The QS committee agreed upon 20 samples per batch as being consistent with EPA and good laboratory practices. The batch size, drives the analysis of additional QC samples, e.g., method blank and laboratory control samples. In addition, we too wrestled with th need for a time limit in this criteria. The consensus reached: "...with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours". The stress here is "start of process" and we realize that as manufactures provide various automated (sequential) devices this may be problematic, however additional QC under such an automated scenario should have decreased impact on laboratory throughput.

2 Request for clarification of the NELAC standard regarding labeling sample containers (NELAC 5.11.1.a). Th letter from the Vermont laboratory indicates "...each of the four (sample) bottles has a distinct label, with two distinct Work Order #3". NELAC (5.11.1.a) requires that: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physica characteristic, such as amber glass, or purple top, is not an acceptable means to identifying the sample". The "distinct label" you have indicated should meet the "unique sample (ID) code" requirement, as long as, " This laboratory code shall maintain an unequivocal link with the unique field ID code assigned each container (5.11.1.b) and "The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration " (5.11.1.d).

Sincerely,

Joseph Slayton, Chair
QS Committee

Comment ID #:	Source of Comments: Dianne Terry, Terry Affiliates, LLC	QS Lead on Response (Name): Donivan Porterfield	
Standard Rev. #: Draft 1/13/99 Section # and QS Standard Narrative (Commentor)	**COMMENT to QS (commentor)**	**QS Leader Provided Proposed Change**	**RATIONALE (from QS Leader)**
5.9.3c)/5.9.4.1e) "Glass microliter syringes are to be considered in the same manner as Class A glassware, but must come with a certificate attesting to established accuracy or the accuracy must be initially demonstrated and documented by the lab"	Statement appears following 5.9.3c) and following 5.9.4.1e). Is it really supposed to be in both places? Seems out of place in 5.9.3.	No change.	In current revision 11 (29 April 1999) indicated duplication has been eliminated. Indicated content is now only present in 5.9.4.1.e.
5.12.2.d) "The laboratory shall establish a record management system for control of laboratory notebooks; instrument logbooks; standards logbooks; and records for data reduction, validation storage and reporting."	Re: "validation storage" Is this requirement for a records management system for records for validation and for storage, or for validation storage (whatever that is)? I.e., is there a comma missing? "..validation, storage.." or possibly it should read "..and for storage of records for data reduction, validation, and reporting;"	"... validation, storage ..."	Yes, believe that a comma is missing. The current phrase going back to about version 4.
5.13.a)17) "clear identification of numerical results with values outside quantitation limits.	Every result, unless equal to the quant limit, is outside the quant limit. Does this item mean "values less than the quantitation limit" or is it meant to address results outside the calibration range as in 5.9.4.2.1.f)	No change.	The current wording is to allow for analytical methods that may have both a lower and upper quantitation level, e.g. the upper quantitation level representing the linear response limit of the technqiue.
5.9.4.2.1.f) "Results of samples not bracketed by initial calibration standards must be reported as having a less certainty, e.g., defined qualifiers or flags or explained in the case narrative."	What about single point calibration? Or when no calibration is required (re: no calibration for Standard Methods 4500-NH3 E for Ammonia-Ion Selected Electrode Using Known Addition, which is approved for NPDES wastewater analysis) Are these non-multipoint calibrations considered a semiquantitative or qualitative analysis that will by definition require a qualifier since there is no multi-point ICAL. For analysis such as pH, if calibration is checked at pH 10 and the sample is pH 11 must it be qualified? What about titration methods such as for chloride using standardized silver or mercuric nitrate with no multi-point calibration (Standard Methods 4500-Cl B & C)? These should not require	No change.	The proposed version of chapter 5 requires at least two calibration points (5.9.4.2.1.i) for those techniques utilizing an initial calibration. Thus the issue of single point calibration is effectively addressed. Where no calibration is required as in the referenced Standard Method the requirement is moot. For the pH example provided the pH 11 result would need to be reported as having less certainty since an initial calibration is being performed and the example

Comment ID #:	Source of Comments: Dianne Terry, Terry Affiliates, LLC	QS Lead on Response (Name): Donivan Porterfield	
	reporting with qualifiers to satisfy 5.9.4.2.1.f). Suggest clarification for this section, such as "Where multi-point initial calibration is required, results of samples not bracketed by initial calibration standards…"		result is outside the example calibration range.
Chapter 1 Policy and Structure, Figure 1-3 = fields of testing, program, method, analyte; Chapter 2, Proficiency Testing 2.1.3 a)b)c) indicates PT fields of testing are program, matrix type, analyte; and Chapter 5, QS 5.4.2j) refers to Chapter 2: "when available, participate in inter-laboratory comparisons and proficiency testing programs. For purposes of qualifying for and maintaining accreditation, each laboratory shall participate in a proficiency test program as outlined in Chapter 2.0."	Is it going to be program/METHOD/analyte or program/MATRIX/analyte? Do not propose to change this section because I agree that reference to the Chapter 2 makes most sense, so you do not end up with inconsistencies if one Chapter changes and the other does not. But could you get some resolution of method vs matrix? Or a confirmation that accreditation is per method, but for purpose of PTs will only need matrix and will apply to more than one method? Would this mean SDWA/WATER/VOA could be analyzed by <u>either</u> GC or GC/MS or is it also meant to be 'technology' based (it does not say that)?	No change.	This topic is not within the jurisdiction of this committee. That question is better directed to the relevant committee.
Initial demonstration of method capability: 5.6.2.c)3)ii) "..initial demonstration of method capability" (changed, was method performance); 5.10.2.1 title "Method Validation/Initial Demonstration of Capability"; 5.10.2.1.a) and d) "..initial demonstration of method performance.."; Appendix C Initial Demonstration of Capability, C1 Initial Demonstration of Capability, C1 first paragraph "initial demonstration of method performance"; C2 first paragraph and 'certificate' title = initial demonstration of capability.	Could this be called the same thing throughout? Since it is <u>"one of"</u> the acceptable methods of establishing <u>not only initial but ongoing</u> method validation it would make more sense to label it as such. If you want to stick with "initial demonstration of capability (IDC)" to be consistent with the newer EPA methods, then use that but label it as a method to achieve the end. Example, as with VOA by GC or VOA by GC/MS, it could indicate "method validation by IDC" or "method performance by IDC" or "demonstration of method capability by IDC" – whatever. See associated comments for Appendix C certificate (next item)	No change.	The current revision seeks this consistency in using the terminology "Demonstration of Capability" (DOC). This terminology covering both the initial and continuing aspects.

Comment ID #:	Source of Comments: Dianne Terry, Terry Affiliates, LLC	QS Lead on Response (Name): Donivan Porterfield	
Appendix C, Certificate Statement 5. Title "Initial Demonstration of Capability" 6. "Method Number, and Analyte, or Class of Analytes or Measured Parameters" 7. There is no reference to the lab SOP/revision number used to establish method capability 8. under "We, the undersigned", Item 5. "All raw data…retained at the facility" Example revised certificate attached.	1. Title, change to "Method Validation/Initial Demonstration of Capability" 2. Change to "Prep/Analysis Method Number(s)" to ensure the prep method is identified 3. Add a line for Lab SOP No(s)/Rev # 4. Change <u>at the facility</u> to <u>by the facility</u>. These records may be archived by the lab, not necessarily on site, as long as readily retrievable. Or is the argument that the off-site archives are agents of the facility so actually it is retained "at" the facility.	Appropriate language to address point 3 to be added. Appendix C (Certification Statement), 5: change "... retained at the facility" to "retained by the laboratory".	1) As noted above the title has been changed. 2) While not specifically calling out "prep" methods the certificate language has been modified to consider the demonstration of multiple methods being certified. 3) Agreed. 4) Agreed.

Comment ID #:	Source of Comments: Dianne Therry, Therry Affiliates, LLC	QS Lead on Response (Name):	
Standard Rev. #: Draft 1/13/99 Section # and QS Standard Narrative (Commentor)	**COMMENT to QS (commentor)**	**QS Leader Provided Proposed Change**	**RATIONALE (from QS Leader)**
5.9.3c)/5.9.4.1e) "Glass microliter syringes are to be considered in the same manner as Class A glassware, but must come with a certificate attesting to established accuracy or the accuracy must be initially demonstrated and documented by the lab"	Statement appears following 5.9.3c) and following 5.9.4.1e). Is it really supposed to be in both places? Seems out of place in 5.9.3.		
5.12.2.d) "The laboratory shall establish a record management system for control of laboratory notebooks; instrument logbooks; standards logbooks; and records for data reduction, validation storage and reporting."	Re: "validation storage" Is this requirement for a records management system for records for validation and for storage, or for validation storage (whatever that is)? I.e., is there a comma missing? "..validation, storage.." or possibly it should read "..and for storage of records for data reduction, validation, and reporting;"		
5.13.a)17) "clear identification of numerical results with values outside quantitation limits.	Every result, unless equal to the quant limit, is outside the quant limit. Does this item mean "values less than the quantitation limit" or is it meant to address results outside the calibration range as in 5.9.4.2.1.f)		
5.9.4.2.1.f) "Results of samples not bracketed by initial calibration standards must be reported as having a less certainty, e.g., defined qualifiers or flags or explained in the case narrative."	What about single point calibration? Or when no calibration is required (re: no calibration for Standard Methods 4500-NH3 E for Ammonia-Ion Selected Electrode Using Known Addition, which is approved for NPDES wastewater analysis) Are these non-multipoint calibrations considered a semiquantitative or qualitative analysis that will by definition require a qualifier since there is no multi-point ICAL. For analysis such as pH, if calibration is checked at pH 10 and the sample is pH 11 must it be qualified? What about titration methods such as for chloride using standardized silver or mercuric nitrate with no multi-point calibration (Standard Methods 4500-Cl B & C)? These should not require		

Comment ID #:	Source of Comments: Dianne Therry, Therry Affiliates, LLC	QS Lead on Response (Name):	
	reporting with qualifiers to satisfy 5.9.4.2.1.f). Suggest clarification for this section, such as "Where multi-point initial calibration is required, results of samples not bracketed by initial calibration standards…"		
Chapter 1 Policy and Structure, Figure 1-3 = fields of testing, program, method, analyte; Chapter 2, Proficiency Testing 2.1.3 a)b)c) indicates PT fields of testing are program, matrix type, analyte; and Chapter 5, QS 5.4.2j) refers to Chapter 2: "when available, participate in inter-laboratory comparisons and proficiency testing programs. For purposes of qualifying for and maintaining accreditation, each laboratory shall participate in a proficiency test program as outlined in Chapter 2.0."	Is it going to be program/METHOD/analyte or program/MATRIX/analyte? Do not propose to change this section because I agree that reference to the Chapter 2 makes most sense, so you do not end up with inconsistencies if one Chapter changes and the other does not. But could you get some resolution of method vs matrix? Or a confirmation that accreditation is per method, but for purpose of PTs will only need matrix and will apply to more than one method? Would this mean SDWA/WATER/VOA could be analyzed by either GC or GC/MS or is it also meant to be 'technology' based (it does not say that)?		
Initial demonstration of method capability: 5.6.2.c)3)ii) "..initial demonstration of method capability" (changed, was method performance); 5.10.2.1 title "Method Validation/Initial Demonstration of Capability"; 5.10.2.1.a) and d) "..initial demonstration of method performance.."; Appendix C Initial Demonstration of Capability, C1 Initial Demonstration of Capability, C1 first paragraph "initial demonstration of method performance"; C2 first paragraph and 'certificate' title = initial demonstration of capability.	Could this be called the same thing throughout? Since it is "one of" the acceptable methods of establishing not only initial but ongoing method validation it would make more sense to label it as such. If you want to stick with "initial demonstration of capability (IDC)" to be consistent with the newer EPA methods, then use that but label it as a method to achieve the end. Example, as with VOA by GC or VOA by GC/MS, it could indicate "method validation by IDC" or "method performance by IDC" or "demonstration of method capability by IDC" – whatever. See associated comments for Appendix C certificate (next item)		
Appendix C, Certificate Statement 5. Title "Initial Demonstration of Capability"	1. Title, change to "Method Validation/Initial Demonstration of	No change	Is clear enough.

Comment ID #:	Source of Comments: Dianne Therry, Therry Affiliates, LLC	QS Lead on Response (Name):	
6. "Method Number, and Analyte, or Class of Analytes or Measured Parameters" 7. There is no reference to the lab SOP/revision number used to establish method capability 8. under "We, the undersigned", Item 5. "All raw data…retained at the facility" Example revised certificate attached.	Capability" 2. Change to "Prep/Analysis Method Number(s)" to ensure the prep method is identified 3. Add a line for Lab SOP No(s)/Rev # 4. Change <u>at the facility</u> to <u>by the facility</u>. These records may be archived by the lab, not necessarily on site, as long as readily retrievable. Or is the argument that the off-site archives are agents of the facility so actually it is retained "at" the facility.		
5.6.2.c)3)iv) "At least four consecutive laboratory control samples with acceptable levels of precision and accuracy"	Does this mean 4 in a row, or in the normal course of analysis the next 4 LCS, which could be, for example, over 3-4 days and interspersed with other standards and samples. Suggest adding sentence similar to wording in Appendix C, C1, c) "the 4 LCS can be prepared and analyzed according to the test method either concurrently or over a period of days, interspersed with calibration standards and samples, but must be consecutive LCS data points."	No change	Is clear enough.
5.6.2.c)3)v "If i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically ~~identical results~~ <u>indistinguishable results.</u>"	Clarification: What is an "authentic sample"? Is it meant to be the potentially contaminated field or investigative sample submitted for analysis? Or can it be any sample from anywhere as long as you have some kind of confirmation that it is positive for the analyte of interest and some experienced analyst got the "same" answer.	delete "authentic"	agree with comment
5.9.4 Calibration, paragraph immediately preceding 5.9.4.1. "<u>Calibration requirements are divided into two parts: (1) requirements for analytical support equipment, and 2) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification</u>."	Consistent format: either use (1) and (2) in the text or use 1) and 2)	no change	editorial

Comment ID #:	Source of Comments: Dianne Therry, Therry Affiliates, LLC	QS Lead on Response (Name):	
5.12.2 b) "All records, including those specified in 5.12.3 and 5.12.4, shall be retained for a minimum of five years from last use. All information necessary for the historical reconstruction of data must be maintained by the laboratory. Records which are stored only on electronic media must be supported by the hardware and software necessary for their retrieval."	1st sentence- if last use was pulling data ~5 years old from storage for a data request from the client or a lawyer or whoever, that the lab must keep it an additional 5 years from that point, even if the requestor "finishes" with it? Should at least indicate "from last use by the laboratory, unless superseded by contractual requirements" or lab is stuck guessing when the client has finished with their report. In the last sentence, conversely does this mean that if you hardcopy the electronic records the hardcopy is sufficient record? For example, if mass spec raw data such as tunes, calibration, spectra for hits are all hard copied the tapes do not have to be maintained (assuming you have no project contractual requirements)? In order to not have to keep tapes, would this mean that for every 5 point you would have to have spectra for each compound hard copied if you did not want to maintain electronic records?	Delete "from last use"	agree
5.4.2f) last sentence "The technical director(s) shall meet the requirements specified in the Accreditation Process (see 4.1.1.1)	4.1.1.1a)c)d). can the specified bachelor's degree be BS or BA? Is the engineering degree any kind (chemical, electrical, mechanical, etc)? 4.1.1.1d), paragraph 2 and its subsections i) through iii): this whole section should probably be new section 4.1.1f)	need to bring to the attention of Chapter 4 Committee	

Comment ID #:	Source of Comments: Virginia NELAC Workgroup	QS Lead on Response: F.Siegelman	
Standard Rev. 10.1 And QS Standard Narrative ~~(To Be Filled in by Commentor)~~	**COMMENT with Rationale to QS (To be filled in by Commentor)** **New Wording for Standard (To Be Filled in by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**
5.4.2.g. "…have a quality assurance officer (however named) who has responsibility for the quality system and its implementation. The quality assurance officer shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical director. Where staffing is limited, the quality assurance officer may ~~also be the technical director or deputy~~ technical director;"	"…have a quality assurance officer (however named) who has responsibility for the quality system and its implementation. The quality assurance officer should have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical director. However, it is possible that neither the QAO nor TD may have access to highest levels of management at which decisions are taken on laboratory policy or resources." This is an important issue for many organizations. The QAO may report directly to the Technical Director (TD) but neither the QAO not TD may have access to senior management even though policy decisions are made at this level. The standards must acknowledge that the Technical Director is capable of managing the laboratory and may not have input into the policy making process. In many situations, to comply with this requirement, the entire organization would have to be restructured.	No change	The text: "at which decisions are taken on laboratory policy" defines the level of management that both the QAO and TD need access to which is not necessarily the senior management .
5.4.2.j. "When available … Chapter 2."	Clarification is needed. If the PT programs stated is the same as in Ch.2, then this statement is unnecessary since PT is required in Ch.2. Please delete to minimize redundancy. If not, please clarify.	No change	the text: "when available, participate in inter-laboratory comparisons and proficiency testing programs. For purposes of qualifying for and maintaining accreditation, each laboratory shall participate in a proficiency test program as outlined in Chapter 2.0." deals with both PT and inter-laboratory comparisons and references Chapter 2.0 Additionally since PT sample supply is going through a

			transition that includes privatization and since PT samples for all matricies are currently not available, the standard as written addresses the current situation. The deletion would require labs to participate in proficiency testing programs that currently do not exsist.
5.5.1.c. "The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services."	This section seems to be saying the same thing as 5.5.2. Would it be more appropriate for this statement to be made in the Quality Manual, which outlines the laboratories policies, procedures and other quality statements? How many places do the statements of commitment to quality need to be confirmed?	No change	I believe we addressesed a comparisionof 5.5.1.c and 5.5.2 in the first set of Virginia comments and I concur with the response given then: "5.5.lc The commentor claim that there repetitiveness with 5.2 in the construction of the quality manual. However, there was a misreading. The management statement of objectives is different from that stated for the laboratory Policies and objectives. Indeed, it may have some similarities, but it is different. I am not sure that there is any way to make the contents of these statements clearer. I would retain the wording as it is."
5.5.1.e. "The quality manual shall be …"	"The quality assurance officer shall ensure that the quality manual is current." Change from passive to active voice. This QAO responsibility should be moved to the list of QAO responsibilities in section 5.4.2.g.	No Change	Current text adequately addresses need.
5.5.2.a. "…a quality statement by top management"	Consolidate quality statements into one document – the Quality Manual. How many quality statements are necessary?	No Change	The current version of the standard is so written. The quality statement is part of the Quality Manual: "The quality

			manual and related quality documentation shall also contain: a) a quality policy statement, including objectives and commitments, by top management;"
5.5.2.c. "the relationship between management, technical operations, support services and the quality system;"	"the relationship between management, technical operations, support services and the quality system e.g. an organizational chart;" Agree with response to previous comments to aid with clarity.	No Change	The inclusion of an organizational chart is already covered elsewhere in the standard.
5.5.2.e. "Job descriptions of key staff and reference to the job descriptions of other ~~staff;~~"	"job descriptions of key staff and reference to the file location of the job descriptions of support staff" Agree with response to previous comments to aid with clarity.	No Change	The reference can include the file location of other staff but the should not be limited to just that.
5.5.2.j. "reference to the calibration and/or verification test procedures used;"	Please clarify to what calibration and verification test procedures are referring.	No change	Requirements are described in sufficient detail in other parts of the standard and repeating requirements in a document can be confusing to the reader.
5.5.2.n. "reference to verification practices…"	Please clarify to what verification practices are referring.	No change	Requirements are described in sufficient detail in other parts of the standard and repeating requirements in a document can be confusing to the reader.
5.5.3.4 Entire section.	Delete section. This is redundant language already described in other chapters. Repeating requirements in a document is confusing to the reader.	No change	While this section does reference other portions of the standard (5.5.4 and chapter 2) this section contains information not found in other places in the standard. It should also be noted that what is offered here is examples and a laboratory's efforts in carrying out Performance Audits does not need to be limited to these.
5.5.4 "are further described in Appendix D."	"Essential quality control procedures shall apply, where applicable, to all testing laboratories. These principles and the manner in which they are implemented is	No change	I concur with the response to a similar comment in the earlier Virginia comments:

	dependent on the types of tests performed by the laboratory (e.g.…) are and further described in Appendix D. Make the first section of Appendix D "General QC Requirements Applicable to all Methods." By consolidating these elements in one place, the reader will not be forced to go back and forth between two sections in the document. This may also prevent misunderstandings and confusion.		**5.5.4. "are further described** in Appendix D." Delete section and move essential QC procedures to Appendix D. The QC procedures only need to be described once, either here or in the appendices. Multiple entries for the same item can result in contradictory statements. **Response:** **The intent of Section 5.5.4 is to include the essential QC elements that are applicable to any methods performed under NELAC accreditation regardless of which category of testing is being accredited. Additional elements unique to each category (or not applicable to all categories) of testing are then listed in appendix D. This hierarchial approach is intended to distinguish common elements which cross all categories from those elements specific to a category. Any redundancies listed in appendix D could be deleted, unless it is intended to add clarity to the appendix D section.**
5.6.2.c.3. (analyst demonstration of continued proficiency)	Add: "vi. For analyses extending over a period exceeding five days (e.g. WET and bacteriological tests), in which multiple analysts are routinely involved in the analysis of a given sample, analysts shall perform a portion of the analyses described in i-v which is representative of their normal laboratory duties." For an analyst to perform an entire chronic WET test,	The current proposed version of the standard addresses this comment.	This has been addressed in the current version of the standard with changes to the text and the utilization of the concept of a work cell .

	from start to finish including dry weights requires that they work 9 consecutive days. Similarly, the "complete" Coliform test by the fermentation method requires 7 calendar days. Several analysts routinely care for these tests over the entire test period. For example, two or three technicians should be able to conduct a chronic mysid test on a blind sample to satisfy this requirement. Of course if the test fails to meet acceptability requirements, all technicians would be affected.		
5.6.2.d. "Documenting all analytical and operational activities of the laboratory."	"Laboratory management shall be responsible for documenting all analytical and operational activities to demonstrate compliance with the quality system requirements." As written, several interpretations could be made as to what these activities consist of.	No Change	The phrase "Laboratory management shall be responsible for" would be redundant because this section of the standard is titled: "**5.6.2 Laboratory Management Responsibilities** " The proposed text of "to demonstrate compliance with the quality system requirements." could be interpreted as putting limitations on the management documentation responsibilities.